10-09-03

Docket 17549 (AP)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Patrick M. Hughes, et al.,	Examiner:
Serial Number: 10/617,468	Art Unit:
Filed: July 10, 2003	Confirmation No.
For: DELIVERY OF AN ACTIVE DRUG TO THE POSTERIOR PART OF THE EYE VIA SUBCONJUNCTIVAL OR PERIOCULAR DELIVERY OF A PRODRUG	Irvine, California

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants provide with regard to the above-identified patent application entitled DELIVERY OF AN ACTIVE DRUG TO THE POSTERIOR PART OF THE EYE VIA SUBCONJUNCTIVAL OR PERIOCULAR DELIVERY OF A PRODRUG, one copy of documents of which they are aware, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. A listing of the documents submitted is set forth on the attached 3 page Information Disclosure Citation (Form PTO-1449).

While these documents may be material pursuant to 37 C.F.R. §1.56, the disclosure is not intended to constitute an admission that the documents are prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material

documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge any fees required or necessary for the filing, processing or entering of this paper or any of the enclosed papers, and to refund any overpayment, to deposit account 01-0885.

Respectfully submitted,

Date: October 7, 2003

Brent A. Johnson
Registration Number 51,851

Please direct all inquiries and correspondence to:

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CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10

I hereby certify that this Information Disclosure Statement and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date October 7, 2003 in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EV295682792US addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Susan Bartholomew
Name of person mailing paper

Date October 7, 2003

Signature of person signing paper

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FORM PTO-1449

LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17549 (AP)	**SERIAL NO.: 10/617,468**
APPLICANT: P. M. HUGHES, ET AL.	**TITLE: DELIVERY OF AN ACTIVE DRUG TO THE POSTERIOR PART OF THE EYE VIA SUBCONJUNCTIVAL OR PERIOCULAR DELIVERY OF A PRODRUG**
FILING DATE: JULY 10, 2003	**GROUP:**

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicabl)
	AA	2002/0049255A1	4/25/02	Gamache, et al.			08/13/01
	AB	2003/0018044A1	1/23/03	Peyman			9/19/02
	AC	4,997,652	3/5/91	Wong			
	AD	4,853,224	8/1/89	Wong			
	AE	5,164,188	11/17/92	Wong			
	AF	5,443,505	8/22/95	Wong, et al.			
	AG	5,476,511	12/19/95	Gwon, et al.			
	AH	5,632,984	5/27/97	Wong, et al.			
	AI	5,766,242	6/16/98	Wong, et al.			
	AJ	5,780,647	7/14/98	Vuligonda et al.			
	AK	5,824,072	10/20/98	Wong			
	AL	6,060,463	5/9/00	Freeman			
	AM	6,378,526 B1	4/30/02	Bowman, et al.			
	AN	6,397,849	6/4/02	Bowman, et al.			
	AO	6,416,777 B1	7/9/02	Yaacobi			
	AP	6,489,335 B2	12/3/02	Peyman			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/n)
	BA	WO 91/19482	12/26/91	PCT			
	BB	WO 93/06856	4/15/93	PCT			
	BC	WO 95/26734	10/12/95	PCT			
	BD	WO 00/07565	2/17/00	PCT			
	BE	WO 02/41910 A2	5/30/02	PCT			

OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

	CA	Alminger, T.B., et al., (Pyridinylmethyl)*Chemical Abstracts*, Vol. 110, 1989, pg. 692, 57664
	CB	Baker, L., et al., Abstract Pars Plana Jet Injection of Ganciclovir, *IOVS*, 1990;31(4):306
	CC	Ball, S., Concentration change and activity of fluorouracil in the external segment of the eye after subconjunctival injection, *Arch Ophthalmol,* Vol. 107, September 1989, pgs 1276-1277
	CD	Bundgaard, H., Design of Prodrugs: Bioreversible derivatives for various functional groups and chemical entities, *Design of Prodrugs (Bundgaard, H., ed.) 1985 Elsevier Science Publishers B.V.*, Biomedical Division, Chp. 1, pg. 1-92.

EXAMINER_____ DATE CONSIDERED _____

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	CE	Bundgaard, H., et al., Prodrugs as drug delivery systems XIX. Bioreversible derivatization of aromatic amines by formation of N-mannich bases with succinimide, *International Journal of Pharmaceutics,* 8(1981) 183-192
	CF	Bundgaard, H., et al., Hydrolysis of N-Mannich bases and its consequences for the biological testing of such agents, *Int. J. Pharm. 1981 9(1), 7-16*
	CG	Bundgaard, H., et al., Phenyl carbamates of amino acids as prodrugs forms for protecting phenols against first-pass metabolism, *Int. J. Pharm.* 81 (1992) 253-261
	CH	Bundgaard, H., et al., Pro drugs as drug delivery systems. X.imides, urea derivatives, amines and other NH-acidic compounds. *Arch Pharm Chemi, Sci. Ed.*, 1980 8(2) 29-52
	CI	Bundgaard, et al., A novel solution-stable, water-soluble prodrug type for drugs containing a hydroxyl or an NH-acidic group, *J. of Medicinal Chemistry,* Vo. 32, No. 12, Dec. 1989, pg. 2503-2507
	CJ	Bundgaard, H., et al., Prodrugs as drug delivery systems. 43. O-acyloxymethyl salicylamide N-mannich bases as double prodrug forms for amines, *Int. J. of Pharm.,* 29 (1986) 19-28
	CK	Bundgaard, H., et al., Hydrolysis of N-(α-hydroxyalkyl) amide derivatives: implications for the design of N-acyloxyalkyl-type prodrugs, *Intl. Journal of Pharm* 22, (1984) 45-56
	CL	Buur, A, et al., Acta Pharm Nord, 1991 3(1) 51-6
	CM	Cheng, Y., et al., Relationship between the inhibition constant (K_I) and the concentration of inhibitor which causes 50 per center inhibition (I_{50}) of an enzymatic reaction, *Biochmical Pharm.,* Vol 22, pp. 3099-3108
	CN	Chiang, C., et al., In vitro and in vivo evaluation of an ocular delivery system of 5-fluorouracil microspheres, *J. of Ocular Pharm and Therapeutics*, Vol. 17, No. 6, 2001; pgs. 545-553
	CO	Joshi, A., Microparticles for Ophthalmic Drug Delivery, *Journal of Ocular Pharmacology*, Vol. 10, No. 1, 1994, pp. 29-45
	CP	Einmahl, S. ("A Novel Route of Ocular Drug Delivery: Suprachoroidal Injections Of A Sustained-Release System", Proceed. Int'l. Symp. Rel. Bioact. Mater., 28, (2001), pp. 293-294
	CQ	Einmahl, S., et al., Abstract, Evaluation of a new biomaterial injected in the suprachoroidal space of the rabbit eye, *IOVS*, 2001;42(4) 1 pg
	CR	Giordano, G.G., et al., Sustained delivery of retinoic acid from microspheres of biodegradable polymer in PVR, *Investigative Ophthalmology & Visual Science,* Aug 1993;34(9), pgs 2743-2751.
	CS	Hansen, K.T., et al., Carbamate ester prodrugs of dopaminergic compounds: synthesis, stability and bioconversion, *J. Pharm Sc.* 1991, 80(8) 793-798
	CT	Herrero-Vanrell, R., et al., Biodegradable PLGA microspheres loaded with ganciclovir for intraocular administration. Encapsulation technique, in vitro release profiles and sterilization process, *Pharmaceutical Research,*Vol. 17, No. 10, 2000, pgs. 1323-1328
	CU	Jensen, E., et al., N-substituted (aminomethyl) benzoate 21-esters of corticosteroids as water-soluble, solution-stable and biolabile prodrugs., *Acta Pharm Nord.,* 1992 4(1) 35042

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	CV	Joshi, A., Microparticulates for ophthalmic drug delivery, *J. of Ocular Pharmacology*, Vol. 10, No. 1, 1994
	CW	Kawase, K., et al ., Mitomycin concentration in rabbit and human ocular tissues after topical administration, *Ophthalmology*, Vol. 99, No. 2, February 1992, pgs. 203-207
	CX	Kondo, et al., Concentration change of fluorouracil in the external segment of the eye after subconjunctival injection, *Arch Ophthalmol 1988;106:1718-1721*
	CY	Maritera, T., et al., Microspheres of biodegradable polymers as a drug delivery system in the vitreous, *Invest Ophthalmol Vis Sci* , 32:1785-1790, 1991
	CZ	Nagy, B., et al., Study on subconjunctival application of capsulated tobramycin, *Ann. Immunol. hung*, 25:355-363; 1985
	CAA	Pinilla, I., et al., Subconjunctival injection of low doses of mitomycin C: effects on fibroblast proliferation, *Ophthalmologica*, 1998;212:306-309
	CBB	Thomsen, K.F., et al., Evaluation of phenyl carbamates of ethyl diamines as cyclization-activated prodrug forms for protecting phenols against first-pass metabolism, *Int. J. Pharm.* 1994, 112(2) 143-52

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